

**Appl. No.** : 10/530,108  
**Filed** : April 1, 2005

### AMENDMENTS TO THE CLAIMS

1. **(Original)** A process for the expansions of TALL lymphocytes, wherein at least  $1 \times 10^9$  cells are grown in homogeneous conditions in a single fermentation unit.
2. **(Original)** The process as claimed in claim 1, wherein said fermentation unit is for anchorage dependent cells.
3. **(Original)** The process as claimed in claim 1, wherein said fermentation unit is a multi-chamber stack.
4. **(Original)** The process as claimed in claim 3, wherein said fermentation unit is a Cell-Factory™.
5. **(Currently amended)** The process as claimed in claim 3, wherein the expansion in the homogeneous system is preceded by a process of pre – expansion in flask until obtaining a number of cells comprised from  $0.7$  to  $1 \times 10^8$ .
6. **(Original)** The process as claimed in claim 5, wherein the cellular density of the inoculum is at least  $0.7 \times 10^6$  cells/ml and is preferably equal to  $0.75 \times 10^6$  cells/ml and, at the harvest time, the density is lower than  $2 \times 10^6$  cells/ml, preferably than  $1 \times 10^6$ .
7. **(Original)** The process as claimed in claim 4, wherein the Cell-Factory™ is a 10-chamber unit.
8. **(Original)** The process as claimed in claim 1, wherein TALL lymphocytes are selected from the group consisting of: TALL-104, TALL-107, TALL-103/2 cell lines, optionally genetically modified.
9. **(Currently amended)** Process according to claim 6 & wherein TALL are TALL-104 lymphocytes, optionally genetically modified.
10. **(Previously presented)** The process as claimed in Claim 1, wherein the complete culture medium in the cell-factory amplification phase also comprises 10% maximum human serum, preferably in the range of 4 to 6%, still more preferably of 5%, and interleukin in a concentration comprised from 80 to 120 IU/ml.
11. **(Original)** The process as claimed in claim 10, wherein interleukin-2 is added to the cell culture every 48-90 hrs.
12. **(Original)** The process as claimed in claim 10, wherein the cell growth in the homogeneous system takes place in an antibiotic-free culture medium.

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13. **(Currently amended)** A process for the preparation of frozen bags of TALL lymphocytes in an amount of at least  $1 \times 10^9$  cells, comprising using ~~characterized in that it comprises~~ the process according to Claim 1.

14. **(Previously presented)** The process as claimed in claim 13, wherein the bag is sealed transversally to the bag filling collet at least in two points to create at least a sampling chamber containing a cell culture volume ranging from 0.1 to 1 ml, physically separated from the culture contained in the bag to perform quality controls.

15. **(Currently amended)** A process for the preparation of a therapeutic dose of at least  $1 \times 10^9$  TALL lymphocytes in a homogeneous culture comprising using ~~characterized in the fact it comprises~~ the process according to Claim 1.

16. **(Currently amended)** The process as claimed in claim 13 ~~15~~, wherein the lymphocytes are TALL-104.

17. **(Withdrawn)** TALL lymphocytes obtainable according to the process of Claim 1 wherein said lymphocytes are characterised by a  $CD3^+$  and  $CD8^+$  immunologic markers expression of 98% min, preferably  $\geq 99\%$ , and by the  $CD56^+$  marker expression of 95% at least, preferably  $\geq 97\%$ .

18. **(Withdrawn)** TALL lymphocytes according to claim 17 characterised by a biological activity, determined by a cytotoxicity assay on appropriate target cells, equal to at least 70% of the control.

19. **(Currently amended)** ~~Process~~ The process according to claim 8 ~~6~~ wherein TALL lymphocytes are TALL-104 lymphocytes.

20. **(Currently amended)** The process as claimed in Claim 9 ~~19~~, wherein the complete culture medium in the cell-factory amplification phase also comprises 10% maximum human serum, preferably in the range of 4 to 6%, still more preferably of 5%, and interleukin in a concentration comprised from 80 to 120 IU/ml.

21. **(Currently amended)** A process for the preparation of frozen bags of TALL lymphocytes in an amount of at least  $1 \times 10^9$  cells, comprising using ~~characterized in that it comprises~~ the process according to Claim 9 ~~19~~.

22. **(Previously presented)** The process as claimed in claim 21, wherein the bag is sealed transversally to the bag filling collet at least in two points to create at least a sampling

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chamber containing a cell culture volume ranging from 0.1 to 1 ml, physically separated from the culture contained in the bag to perform quality controls.

23. **(Currently amended)** The process for the preparation of a therapeutic dose of at least  $1 \times 10^9$  TALL lymphocytes in a homogeneous culture ~~characterized in the fact it comprises~~ comprising using the process according to Claim 20.

24. **(Withdrawn)** TALL lymphocytes obtainable according to the process of Claim 20 wherein said lymphocytes are characterised by a  $CD3^+$  and  $CD8^+$  immunologic markers expression of 98% min, preferably  $\geq 99\%$ , and by the  $CD56^+$  marker expression of 95% at least, preferably  $\geq 97\%$ .